

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG
MDL No. 2738**

THIS DOCUMENT RELATES TO ALL CASES

**THE PLAINTIFFS' STEERING COMMITTEE'S REPLY TO
DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON
CONSUMER INC.'S MEMORANDUM OF LAW IN RESPONSE TO THE
PLAINTIFFS' STEERING COMMITTEE'S OMNIBUS BRIEF
REGARDING *DAUBERT* LEGAL STANDARD AND SCIENTIFIC
PRINCIPLES FOR ASSESSING GENERAL CAUSATION**

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The Plaintiffs’ Steering Committee (“PSC”) submits this reply to the Johnson & Johnson Defendants’ (“J&J”) Response to *The Plaintiffs’ Steering Committee’s Omnibus Brief Regarding Daubert Legal Standards and Scientific Principles for Assessing General Causation* (ECF No. 9732) (“PSC General Causation Brief”).¹

I. J&J HAS NOT MET ITS BURDEN OF DEMONSTRATING THAT ITS EXPERTS USED RELIABLE SCIENTIFIC METHODS TO REACH THEIR OPINIONS

J&J argues that its “experts do not have a burden to disprove the elements of Plaintiffs’ claims, including causation, and are instead free to rest on critiques of Plaintiffs’ experts’ methods.” In essence, J&J is arguing that it has no burden to meet in this *Daubert* proceeding because it is the PSC that bears the burden of proof.² J&J contends that all it needs to do is proffer experts who criticize the PSC’s experts and upon doing so, its experts’ opinions are automatically deemed admissible – end of story.

J&J misconstrues its burden. It is well-established that the burden is on the party offering the expert to demonstrate that the expert used a reliable scientific

¹ *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Memorandum of Law in Response to the Plaintiffs’ Steering Committee’s Omnibus Brief Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation*, (ECF No. 9882) (“Defs. Opp.”).

² Defs. Opp. at 2-3.

method to reach his or her opinions.³ Therefore, since J&J has proffered experts, it has a burden to show that its experts are qualified, utilized a reliable methodology in either giving an affirmative opinion or criticizing the PSC's experts, and that their opinions fit the case. Even if the opinion is merely one criticizing the PSC's experts, the criticisms must meet these requirements, and if they do not, then they should be excluded.

Moreover, J&J's experts do more than merely criticize the PSC's experts. They offer express opinions on a wide variety of substantive matters, including whether Talcum Powder Products contain asbestos or other carcinogens (such as fibrous talc, heavy metals, fragrances, etc.); whether there is evidence of biological plausibility (i.e., migration and/or inhalation, and resulting inflammation); and other matters. Like the opinions criticizing the PSC's experts, the substantive opinions of J&J's experts must likewise meet the threshold requirements under *Daubert*, and if they do not, then they should be excluded.

As set forth in the PSC's *Daubert* motions seeking to exclude J&J's experts and the opinions of those experts, J&J has not met its burden because a number of

³ *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 198 F. Supp. 3d 446, 451 (E.D. Pa. 2016) (“[I]t is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence.”); *see In re TMI Litig.*, 193 F.3d 613, 705 (3d Cir. 1999) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)); *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 466, 466, 468 (E.D. Pa. 2014).

its experts are not qualified to render certain opinions and they have failed to use reliable scientific methods to reach their affirmative opinions, including their opinions criticizing the PSC's experts. In this regard, the PSC has filed the following affirmative *Daubert* challenges to J&J's witnesses:

- *The Plaintiffs' Steering Committee's Memorandum of Law In Support of Its Motion To Exclude The Opinions Of Defendants' Epidemiology Experts Drs. Ballman, Merlo, Diette & Borak;*⁴
- *The Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions of Robert Kurman, M.D.;*⁵
- *The Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions of Defendants' Toxicology Experts Drs. Mossman, Moore and Tuttle;*⁶
- *The Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions of Defendants' Molecular Biologists Drs. Shih, Neel, Boyd, and Birrer;*⁷
- *The Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions and Testimony of Defendants' Gynecology-Oncology Experts Dr. Cheryl Saenz and Dr. Kevin Holcomb;*⁸

⁴ ECF No. 9737-1 ("PSC Epi. Brief").

⁵ ECF No. 9734-1 ("PSC Kurman Brief").

⁶ ECF No. 9739-1 ("PSC Toxicology Brief").

⁷ ECF No. 9743-1 ("PSC Molecular Biology Brief").

⁸ ECF No. 9735-1 ("PSC GYN-ONC Brief").

- *The Plaintiffs’ Steering Committee’s Memorandum of Law in Support of its Motion to Exclude the Geologic Testing Opinions of Drs. Ann G. Wylie and Melinda Darby Dyar;*⁹ and,
- *The Plaintiffs’ Steering Committee’s Memorandum of Law in Support of its Motion to Exclude the Geologic Opinions of Drs. Mary Poulton and Laura Webb.*¹⁰

J&J has filed its oppositions to these motions and the PSC will file their replies contemporaneous with the filing of this brief.

II. THE PSC HAS MADE MERITORIOUS CHALLENGES TO THE QUALIFICATIONS OF J&J’S EXPERTS PURSUANT TO RULE 702’S QUALIFICATIONS REQUIREMENT AND HAS NOT ASKED THE COURT TO APPLY THE QUALIFICATIONS REQUIREMENT IN AN UNEVEN MANNER

J&J contends that the PSC has taken an extreme position in challenging the qualifications of J&J’s experts.¹¹ As an example, J&J argues that the PSC “goes so far as to challenge Dr. Mary Poulton’s qualifications to offer geology opinions because her Ph.D. is in geological engineering” and “she does not possess a geology degree.”¹² It is ironic that with all the accusations of cherry-picking by both parties, J&J picks a single-line from the PSC’s motion to mischaracterize the qualifications challenge the PSC has made against Dr. Poulton. The PSC’s argument regarding Dr.

⁹ ECF No. 9741-1 (“PSC Geology Testing Brief”).

¹⁰ ECF No. 9745-1 (“PSC Geology Brief”).

¹¹ Defs. Opp. at 6.

¹² *Id.*

Poulton's lack of qualifications is based on much more than the fact she does not possess a geology degree (which she does not).

To demonstrate the merit of the qualifications challenges the PSC has made against J&J's experts, the below chart summarizes the basis for the PSC's qualifications challenges, discussing not only Dr. Poulton, but other J&J experts who lack qualifications relevant to this matter:

**SUMMARY OF THE PSC'S CHALLENGES
TO THE QUALIFICATIONS OF J&J'S EXPERTS**

GEOLOGY¹³ AND GEOLOGICAL TESTING¹⁴	
Mary Poulton, Ph.D.	<p>Dr. Poulton opines that the PSC's experts, Drs. Cook and Krekeler, have incorrectly concluded that there is asbestos at the talc mines used by J&J. The PSC challenges her qualifications to offer such an opinion and criticism, not merely because she does not have a geology degree (which she does not), but also because she has no relevant experience to render such an opinion:</p> <ul style="list-style-type: none"> • Her primary academic focus is mine safety. • She admits she is not a geology expert. • She has not reviewed the relevant scientific literature regarding the geology of the deposits from which J&J sourced talcum powder for its products. • She is not an expert in the geology of Vermont talc deposits and does not know where the mines are located. • She has not published any peer reviewed papers on talc deposits or deposits containing asbestos. • She has never designed, directed or been consulted regarding drilling programs for purposes of mineralogic exploration.

¹³ See deposition testimony and exhibits cited in and attached to PSC Geology Brief.

¹⁴ See deposition testimony and exhibits cited in and attached to PSC Geology Testing Brief.

	<ul style="list-style-type: none"> • She has never been hired to perform mineralogic exploration for purposes of economic development. • She has never designed, directed or been consulted regarding a mine plan, an open-pit mine, the operation of an underground mine or a beneficiation or processing plant.
Laura Webb, Ph.D.	<p>Dr. Webb opines that the PSC's experts, Drs. Cook and Krekeler, have incorrectly concluded that there is asbestos in the talc mines used by J&J. The PSC challenges her qualifications to offer such an opinion and criticism because:</p> <ul style="list-style-type: none"> • Her primary academic focus is calculating the age of rocks, not identifying talc or asbestos in rocks or at a mine. • She has never examined talc for the purpose of identifying asbestos. • She has never performed any academic research or studies focused on talc or asbestos. • She has never published any peer-reviewed articles on: <ul style="list-style-type: none"> ○ asbestiform amphiboles in talc; ○ the methodological approaches for identifying asbestiform minerals in talc; or, ○ talc deposits in Vermont, Italy, or China used to source J&J's <i>Baby Powder</i> and <i>Shower-to-Shower</i>. • She has never reviewed peer-reviewed literature or other materials on any issues relating to asbestos in talc. • She has never participated in any conferences or forums pertaining to the topic of asbestos in talc. • She has never been involved in research or work of any kind designed to investigate the presence of asbestos in geologic formations. • She has never set foot in much less worked in a talc mine, including the mines in nearby southern Vermont that were used to source J&J's Talcum Powder Products. • She has never designed talc mine operations or consulted on talc mine operations. • She has never designed drill core sampling protocols for a talc mine, blast hole sampling protocols, open pit mining operations, or underground mining operations; and, • She has never reviewed any talc mine planning maps or drill cores.

Anne Wylie, Ph.D.	<p>The PSC challenges the qualifications of Dr. Wylie to offer an opinion challenging the opinions of Drs. Longo and Rigler that are based on their TEM testing of talcum powder for asbestos because:</p> <ul style="list-style-type: none"> • She has no experience in the use of TEM to test for asbestos. • If asked, she could not use TEM to evaluate a bulk sample for asbestos.
Melinda Dyar, Ph.D.	<p>Dr. Dyar criticizes the opinions of Drs. Longo and Rigler relating to their testing of historical talc samples. The PSC challenges her qualifications to offer such opinions and criticisms because:</p> <ul style="list-style-type: none"> • She has no personal experience testing samples for the purpose of determining if asbestos is present. • She has never tested a talcum powder sample for asbestos. • She spends “no” time per year analyzing samples for asbestos. • While she spends 3000 hours in the lab per year, less than 10 hours are spent analyzing samples which may include asbestos. • Most of her knowledge about asbestos testing protocols and standards comes from litigation work only. • She has never published about talcum powder or on the appropriate methodology for testing talcum powder. • She has never published about how to determine whether asbestos exists in a bulk sample or product. • She has never published about how to use EDS, AAED or PLM testing. • She has no knowledge about J&J’s talc mines or what accessory minerals are found in the mines.
MOLECULAR BIOLOGY¹⁵	
Benjamin G. Neel, M.D., Ph.D.	<p>The PSC challenges the qualifications of Dr. Neel, Dr. Shih and Dr. Boyd to provide any testimony or opinions about the relative strengths and weaknesses of the epidemiological studies because:</p>

¹⁵ See deposition testimony and exhibits cited in and attached to PSC Molecular Biology Brief.

Ie-Ming Shih, M.D., Ph.D	<ul style="list-style-type: none">• None are qualified to render opinions about strength and weaknesses of the studies since they admit they are not epidemiology experts and defer to epidemiology experts on questions about epidemiology.• Dr. Boyd acknowledges that he is not qualified on the question of migration and stated that he is not offering any opinions regarding migration.
Jeffrey Boyd, Ph.D. ¹⁶	
Benjamin G. Neel, M.D., Ph.D.	The PSC challenges the qualifications of Dr. Neel and Dr. Shih to provide any testimony or opinions about general causation based on a Bradford Hill analysis because: <ul style="list-style-type: none">• Any such opinion ventures far outside their expertise in molecular biology.• Each admitted they were not experts in Bradford Hill factors for assessing causality• Neither applies Bradford Hill as part of their practice.• Both were unable to discuss Bradford Hill in detail at their depositions.
Ie-Ming Shih, M.D., Ph.D.	
TOXICOLOGY ¹⁷	
Kelly Tuttle, Ph.D.	The PSC challenges the qualifications of Dr. Tuttle to provide any testimony or opinions regarding the epidemiological and biological studies because: <ul style="list-style-type: none">• Her field of science is toxicology and industrial hygiene . She is not an epidemiologist and has never taken a course which required an epidemiology textbook.

¹⁶ The PSC's motion as to Dr. Boyd should be granted since J&J states in its motion that "Dr. Boyd could not have been clearer at his deposition that he is **not** offering any opinions on epidemiology." *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc's Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude the Opinions of Defendants' Molecular Biologists Drs. Neel, Shih, Boyd & Birrer* (ECF No. 9873) ("Defs. Cell Biology Opp.") at 18.

¹⁷ See deposition testimony and exhibits cited in and attached to PSC Toxicology Brief.

	<ul style="list-style-type: none"> • Her testimony revealed her inexperience in this field and demonstrated that she lacks a basic understanding of epidemiologic and mechanistic concepts . • She has not reviewed the totality of relevant scientific literature regarding talcum powder products and limited her review to studies addressing certain heavy metals and fragrances. • Her limited review of the toxicological and mechanistic properties of specific constituent parts of talcum powder products render her opinions on causation unreliable.
	<p>The PSC challenges the qualifications of Dr. Tuttle to provide any testimony or opinions about general causation based on a Bradford Hill analysis because she lacks relevant expertise in conducting a Bradford Hill analysis:</p> <ul style="list-style-type: none"> • While she testified she uses “the Hill criteria throughout [her] work as a toxicologist” and uses it “regularly in assessing the scientific literature in the body of science,” she admitted she has never used it to assess the safety of a manufactured product. • None of Dr. Tuttle’s unrelated publications (and none related to the issues in this case) addresses a Bradford Hill analysis. • Dr. Tuttle had to plagiarize her discussion of Bradford Hill because she lacks the requisite knowledge of basic epidemiology, general causation, and toxicological concepts, rendering her opinions unreliable.
Nadia Moore, Ph.D.	<p>The PSC challenges the qualifications of Dr. Moore to provide testimony or opinions about the toxicological properties of talcum powder or ovarian cancer because she has no experience, education, or training on either topic:</p> <ul style="list-style-type: none"> • She has no laboratory experience with talcum powder, including <i>in vitro</i> studies or analysis of talcum powder by X-ray diffraction (XRD), polarized light microscopy (PLM), or transmission electron microscopy (TEM). <p>The PSC challenges the qualifications of Dr. Moore to provide testimony or opinions rebutting or criticizing the expert testimony and research of Dr. Ghassan Saed, a cancer biologist because she:</p>

	<ul style="list-style-type: none"> • lacks training, education, or experience in cancer biology; • has not conducted any original research involving <i>in vitro</i> studies; and • does not have the expertise or training in cancer biology to address Dr. Saed's methodology.
	<p>The PSC challenges the qualifications of Dr. Moore to provide testimony or opinions rebutting or criticizing the opinions of Dr. Longo because she has:</p> <ul style="list-style-type: none"> • never tested talcum powder or any other bulk sample for the presence of fibrous material such as asbestos or fibrous talc; and, • no training, expertise or experience in the area of the analysis of samples for the presence of fibrous material.
	<p>The PSC challenges the qualifications of Dr. Moore to provide testimony or opinions about the presence or absence of fibrous talc particles within the J&J Talcum Powder Products because she:</p> <ul style="list-style-type: none"> • defers to other experts as to the presence of fibrous talc within the finished product; and, • acknowledged, that the portions of her report that pertain to composition (including the presence of asbestos and fibrous talc) or testing of talcum powder products lie outside the scope of her expertise and, therefore, any opinions in her report that purport to comment on those topics should be excluded.
GYNECOLOGY-ONCOLOGY¹⁸	
Cheryl Saenz, M.D.	<p>The PSC challenges Dr. Saenz's qualifications to provide testimony and opinions criticizing the PSC's epidemiology expert Dr. Smith-Bindman and, specifically, the methodology Dr. Smith-Bindman employed in designing and performing her meta-analysis, because Dr. Saenz is not an epidemiologist and because of her lack of training and expertise in designing meta-analyses.</p>

¹⁸ See deposition testimony and exhibits cited in and attached to PSC GYN-ONC Brief.

PATHOLOGY¹⁹	
Robert Kurman, M.D.	The PSC challenges Dr. Kurman's qualifications to provide testimony and opinions regarding asbestos, its carcinogenic effects on tissue, and to criticize Dr. Kane's asbestos/talc and mesothelioma/high grade serous ovarian carcinoma analogies. Dr. Kurman acknowledged three times in his deposition that he is not an expert on asbestos and asbestos-related diseases.
	<p>The PSC challenges Dr. Kurman's qualifications to provide opinions on general causation of talcum powder, asbestos and ovarian cancer because he:</p> <ul style="list-style-type: none"> • acknowledged he is not an expert in cancer biology; • never conducted a single study to observe the effects of talcum powder on gynecologic tissue (or any tissue for that matter); • never read the available cell studies observing talc's effect on cells; • never studied the effects of talc and/or asbestos in tissue; • has never looked at talc in tissue under a microscope; and • never published or even lectured on any topic related to talc.

What is clear is that even under the Third Circuit's liberal qualification standard, many of J&J's experts should be prohibited from providing testimony and opinions because they have ventured far outside their areas of expertise. Moreover, as set forth in the PSC's response to J&J's conditional qualifications motion, the

¹⁹ See deposition testimony and exhibits cited in and attached to PSC Kurman Brief.

PSC's experts have "stayed-in-their-lane" in providing opinions limited to their area of expertise.²⁰

III. J&J'S EXPERTS HAVE ENGAGED IN CHERRY-PICKING BY IGNORING MATERIALS THAT ARE UNFAVORABLE TO J&J'S POSITION OR THAT ARE INCONSISTENT WITH THEIR OPINIONS

J&J cannot (and does not) deny the fact that its experts ignored important scientific material that was contrary to their opinions and chose to review only material that was supportive. Unable to deny these facts, J&J asks the Court to overlook this methodological failure by arguing that it is not "cherry-picking" because, to paraphrase J&J's argument, "it only happened a little-bit."²¹

Notwithstanding J&J's contention, it did not only happen a little bit. On the contrary, J&J's experts have engaged in precisely the type of cherry-picking that J&J describes in its brief: a systematic and slanted effort to limit consideration of material to only that which is favorable to or supports J&J's position.²² In its *Daubert* motions, the PSC has provided the Court with innumerable examples and will further elaborate in its individual replies to J&J's responses. One example is the improper elevation of talcum powder cohort studies as the *best* evidence that no association

²⁰ See *The Plaintiffs' Steering Committee's Memorandum of Law in Response and Opposition to J&J's Conditional Motion to Exclude Certain Plaintiffs' Experts' Opinions for Lack of Qualifications*. (ECF No. 9886) ("PSC Qualifications Opp.").

²¹ Defs. Opp. at 8-11.

²² *Id.* at 8-12.

exists between Talcum Powder Products and ovarian cancer. Further, J&J's experts consider only studies with statistically significant results and ignore the positive risk ratios and confidence intervals in non-statistically significant ones, summarily dismissing them as "inconsistent." That is not only "cherry-picking," it is "significance testing," which is itself a flawed, unreliable and prohibited methodology, as the PSC has explained in detail in numerous other briefs.²³

The PSC's experts have provided detailed and specific reasons for their opinions why cohort studies alone do not tell the whole story, as J&J contends. The PSC experts have explained in detail how the body of scientific evidence *as a whole*, including all observational studies, meta-analyses of those studies, as well as the biologic and geologic evidence supports their conclusion that Talcum Powder Products cause ovarian cancer. In comparison, J&J's experts have failed to adequately explain why they chose to cherry-pick the cohort studies and failed to consider the totality of the evidence to support their conclusions. For this reason alone, their opinions are unreliable and should be excluded by the Court.

²³ See *The Plaintiffs' Steering Committees' [Corrected] Omnibus Memorandum Of Law In Response And Opposition To Defendants' Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion To Exclude Plaintiffs' General Causation Opinions* (ECF No. 9914) ("PSC General Causation Opp."); PSC Epi. Brief; and the *Plaintiffs' Steering Committee's Memorandum of Law In Reply to Defendants Johnson & Johnson And Johnson & Johnson Consumer Inc.'s Memorandum of Law In Opposition to Plaintiffs' Motion To Exclude The Opinions of Defendants' Epidemiology Experts* ("PSC Epi. Reply"), being filed concurrently.

J&J characterizes as “obsessive” the PSC’s effort to bring to the attention of the Court Health Canada’s draft report. J&J goes so far as to describe this effort as an “obsessive focus.” While it is true that some of J&J’s experts completely ignored or remained silent about the Health Canada findings by their independent scientists, J&J cannot deny these findings. J&J cannot deny that these findings were made outside of litigation and the scientists use the very same methodology and analyze the same studies as the PSC’s experts. J&J’s worry is that a strong indicia presents itself that the PSC’s experts in this litigation used a reasonable methodology, one that other scientists use.

J&J’s strategy to marginalize Canadian regulatory action is not surprising. J&J can no longer repeat their mantra that no regulatory body in the world has found talcum powder products to be a causative agent in the development of ovarian cancer. Whether considered final or interim conclusions, the fact remains that based upon the totality of information Health Canada concluded and published that “[t]here is support for an association of inflammation and increased risk of ovarian cancer,”²⁴ and that “available data are indicative of causal effect.”²⁵ In fact, Health Canada published a poster (below)²⁶ illustrating ways to minimize talcum powder product

²⁴ Health Canada Assessment at 18, attached to the PSC General Causation Opp. as Exhibit 56.

²⁵ *Id.* at iii, 21.

²⁶ Exhibit A, Health Canada poster.

exposure and that specifically warns that the application of Talcum Powder Products to the female genitals “May Cause Ovarian Cancer”:

A DRAFT SCREENING ASSESSMENT OF TALC PROPOSES THAT IT MAY BE HARMFUL TO HUMAN HEALTH.

AREAS OF CONCERN




INHALATION

Inhalation of fine particles of TALC from loose powder products such as:

- > baby powder
- > body powder
- > face powder
- > foot powder

THESE PRODUCTS MAY DAMAGE THE LUNGS



FEMALE GENITALS

Exposure of the female genitals to products containing TALC such as:

- > body powder
- > baby powder
- > genital antiperspirants and deodorants
- > diaper and rash creams
- > body wipes
- > bath bombs

THESE PRODUCTS MAY CAUSE OVARIAN CANCER

To minimize your exposure to certain products containing TALC, you can:


- 1 AVOID INHALING LOOSE TALC POWDER**
- 2 AVOID FEMALE GENITAL EXPOSURE TO TALC**
- 3 CHOOSE A TALC-FREE ALTERNATIVE**

If you are still concerned, speak to your doctor or health care provider.

If the final screening assessment confirms that TALC is harmful to human health, the Government of Canada will take action to **manage the risks** identified.

For more information, please visit Canada.ca/Health and search for TALC.

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 **Canada**

As J&J stated in its General Causation Brief: “[T]he Third Circuit has stressed, ‘any step *that* renders the analysis unreliable under the *Daubert* factors

renders the expert's testimony inadmissible.'"²⁷ It follows then that the extensive cherry-picking by J&J's experts (which J&J admits occurred) renders the opinions of its experts that cherry-picked unreliable under *Daubert*.

VI. J&J'S ARGUMENT -- THAT THE PSC HAS ATTEMPTED TO TURN THE SCIENTIFIC WORLD ON ITS HEAD WITH RESPECT TO STATISTICAL SIGNIFICANCE AND THE HIERARCHY OF SCIENTIFIC EVIDENCE -- IS A MISCHARACTERIZATION OF THE PSC'S ARGUMENT AS WELL AS AN ATTEMPT BY J&J TO MISLEAD THE COURT ABOUT RELIABLE SCIENTIFIC PRINCIPLES GOVERNING EPIDEMIOLOGY²⁸

In nothing short of a sleight-of hand, J&J ignores the PSC's argument that J&J's experts use a flawed mechanical two-step methodology to sort studies by

²⁷ See *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Memorandum of Law in Support of Motion to Exclude Plaintiffs' Experts' General Causation Opinions*, (ECF No. 9736.) ("Defs. General Causation Brief") at 29, citing *In re Zolof (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017) and *Perry v. Novartis Pharm. Corp.*, 564 F. Supp. 2d 452, 459 (E.D. Pa. 2008).

²⁸ The PSC has responded extensively in other briefing to J&J's arguments in *Section IV* on pages 12 and 20 of Defs. Opp. about the false claim that the PSC has attempted to turn the scientific world on its head. This is simply a false accusation. See PSC General Causation Opp. and PSC Epi Brief. Moreover, the PSC addresses this meritless argument in further detail in the PSC's reply to *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude the Opinions of Defendants' Epidemiology Experts* (ECF No. 9871) ("Defs. Epi. Opp."), which is being filed concurrently (PSC Epi. Reply). The PSC refers the Court to that briefing for a more fulsome response but, because J&J reasserted its argument in responding to the PSC General Causation Brief, the PSC provides a short reply which demonstrates that as dramatic as J&J's argument is, it is equally false and misleading.

“significance testing” and “hierarchy of evidence” based on generic study designs. J&J does so by not addressing head on the flawed and unscientific two-step methodology used by its experts. Rather J&J misdirects the Court by making an evasive, specious and false argument that the PSC is attempting to turn the scientific world on its head.²⁹ Nothing can be further from the truth.

A. The PSC and Its Experts Do Not Contend That “Statistical Significance is Irrelevant”

J&J’s “significance testing” argument is disingenuous. The PSC and its experts do not reject statistical significance, but they do reject the flawed methodology of “significance testing.”³⁰ *Statistical significance* is a different epidemiological concept than *significance testing*. In defending the first methodologic step taken by its experts, J&J sows confusion by conflating “significance testing” with statistical significance. They are not the same, and J&J ignores the scientific distinction. Instead, J&J reframes the PSC’s challenge, arguing that it is the PSC’s view that “statistical significance... does not matter” and that the PSC allegedly claims that statistical significance has been “universally condemned by both the epidemiologic and statistical communities...”³¹

²⁹ Defs. Opp. at 12.

³⁰ See PSC Epi. Reply at 6.

³¹ Defs. Opp. at 23-24.

Notwithstanding J&J's argument, neither the PSC nor its experts "attack the long-established concept of statistical significance."³² Nor do the PSC's experts *disregard* statistical significance. The PSC and its experts fully agree with the *Zoloft* court that although there may be a casual association *in the absence* of any statistically significant studies in some instances, statistical significance remains a useful metric for determining whether the results of a given study likely show a real association.³³

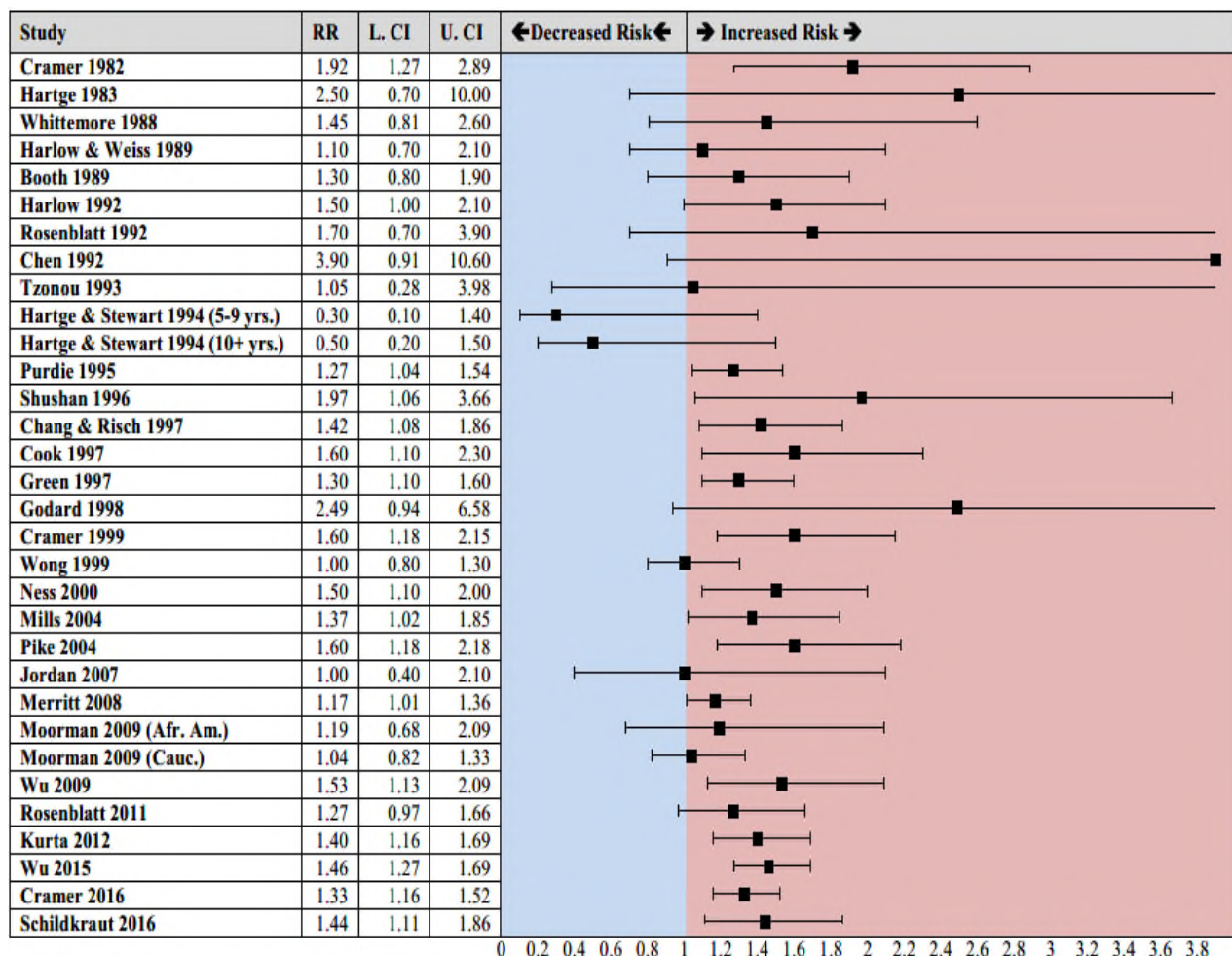
Therefore, and fundamentally, the PSC and its experts do not "attack" statistical significance. Nor would it be in its best interests to do so – since the majority of studies show a statistically significant increase risk between the genital use of talcum powder and epithelial ovarian cancer. Illustrative of the significant risk association is the Forest-plot below³⁴ which demonstrates that almost all case-

³² Defs. General Causation Brief at 5.

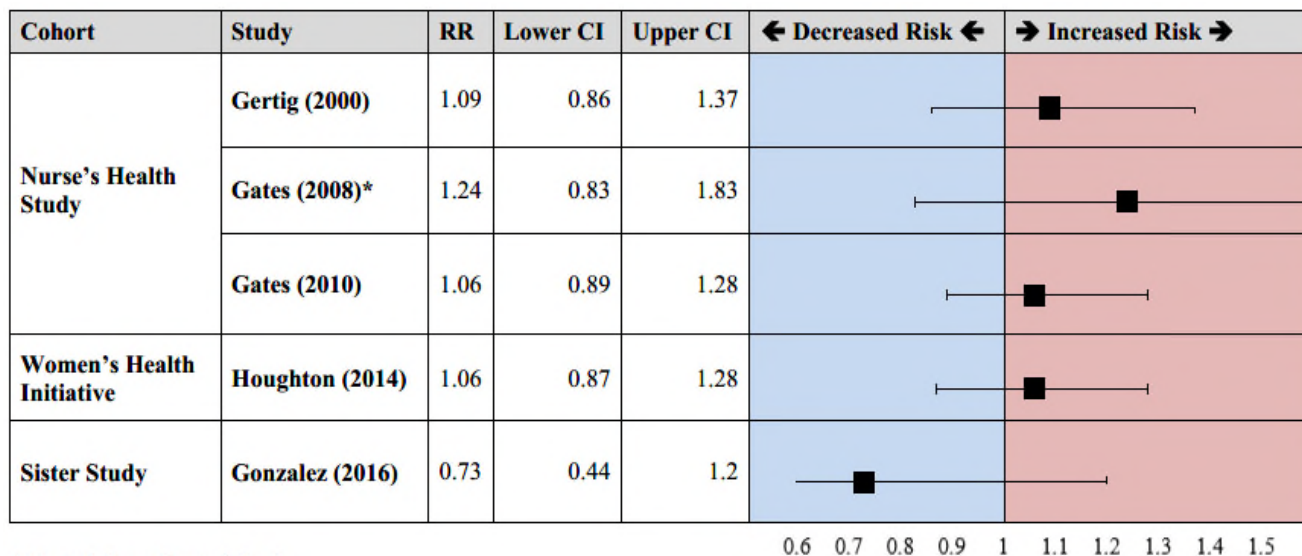
³³ *See In re Zoloft*, 858 F.3d at 793; *see also, In re Roundup Prod. Liab. Litig.*, No. 16-md-02741-VC, 2018 WL 3368534, at *8 (N.D. Cal. July 10, 2018); *compare with In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, No. 2436, 2016 WL 4039286, at *2 (E.D. Pa. July 28, 2016) (finding causation in the absence of statistically significant observational or clinical trial data).

³⁴ Siemiatycki Rep. at 95-97, attached to PSC General Causation Opp. as Exhibit 4.

control studies, regardless of their study design, show a consistent increased risk between use of Talcum Powder Products and ovarian cancer.



Moreover, as illustrated in the following Forest-plot, the results of 4 of the 5 published studies regarding the three cohorts showed a positive association and the confidence intervals of all 5 were consistent with the 20-25% increased risk seen in the case-control studies:



The PSC's experts (and independent entities like Health Canada, for example) relied *heavily* on the statistically significant evidence to conclude that Talcum Powder Products are associated with ovarian cancer. These include the following facts:

- Over half of the studies showed statistically significant results between 1.1-1.7;³⁵
- The 8 published and several unpublished meta-analyses, which are designed to increase the power of any one study to detect an effect, showed a statistically significant risk between 1.25-1.45;³⁶ and,
- The Penninkilampi (2018) meta-analysis of **cohort** studies (the studies that J&J believes are most reliable), demonstrated a

³⁵ See exhibits, reports and deposition testimony cited in fn. 296 of the PSC General Causation Opp.

³⁶ See exhibits, reports and deposition testimony cited in fn. 297 of the PSC General Causation Opp.

statistically significant increased risk of serous invasive ovarian cancer.³⁷

The PSC's experts did what good careful scientists do – they looked at what the data actually described. They analyzed and assessed whether the non-significant risk estimate was positive for an association and assessed the confidence intervals to see if they included the statistically significant results seen in the case-control studies.³⁸ Indeed, the *Reference Manual* describes confidence intervals to be “more valuable than [statistical tests]”³⁹ and the Third Circuit agrees.⁴⁰ With respect to the talcum powder-ovarian cancer data specifically, the PSC's experts noted that:

³⁷ See exhibits, reports and deposition testimony cited in fn. 298 of the PSC General Causation Opp.

³⁸ See exhibits, reports and deposition testimony cited in fn. 299 of PSC General Causation Opp.

³⁹ *Ref. Man.* at 253. Confidence Intervals are defined as “[a]n estimate, expressed as a range, for a parameter. For estimates such as averages or rates computed from large samples, a 95% confidence interval is the range from about two standard errors below to two standard errors above the estimate. Intervals obtained this way cover the true value about 95% of the time, and 95% is the confidence level or the confidence coefficient.”

⁴⁰ The Third Circuit described confidence intervals (i.e., the range of values that would be found in similar studies due to chance, with a specified level of confidence) and their use as an alternative to statistical significance in *DeLuca by DeLuca v. Merrell Dow Pharm., Inc.*, 911 F.2d 941, 948–49 (3d Cir. 1990). See also *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 24–25 (1st Cir. 2011) (recognizing the difficulty of obtaining statistically significant results when the disease under investigation occurs rarely and concluding that district court erred in imposing a statistical significance threshold).

- The non-significant risk ratios for the remaining studies, including the cohort studies, were positive; and,
- The confidence intervals reported for the remaining non-significant studies, including the cohort studies, overlapped 1.2-1.25 meaning that the true risk seen in these studies could have been as high as 20-25% to a 95% certainty thereby being consistent with both the statistically significant case control studies and the meta-analyses.⁴¹

Sprinkled throughout J&J's opposition are allegations that anybody that disagrees with J&J's courtroom science and its experts' conclusions are "outliers." J&J does not limit its "outlier allegations to the PSC's experts, but rather J&J also accuses Drs. Rothman and Greenland of being outliers, despite the fact that they are giants in the field of epidemiological science.

B. J&J's "Hierarchy of Evidence" Argument Is Similarly Contrary To Basic Epidemiologic Principles

J&J also defends the practice its experts use of "sorting" the talcum powder studies by a "Hierarchy of Evidence." This "studies sorting" methodology mandates, with no further analysis, that certain observational studies are more "reliable" and therefore trump other studies which it deems "less reliable." By adopting a hierarchy, J&J and its experts are able to argue that only the talcum powder cohort studies matter and all case control studies and meta-analyses can and should be ignored. J&J's experts calls this a "fundamental" and "established"

⁴¹ See exhibits, reports and deposition testimony cited in fn. 302 of PSC General Causation Opp.

hierarchy of scientific evidence, advocate that studies be categorically sorted accordingly and that anyone who rejects this rigid algorithm is an “outlier.” The PSC has fully briefed this issue, demonstrating that “studies sorting” (and “significance testing”) is unreliable.⁴²

It is important, to emphasize that the *Reference Manual* itself does *not* support the view that J&J puts forth. There is a “hierarchy” in the *Reference Manual*, but that hierarchy treats observational studies *equally* and does *not* distinguish between cohort or case control studies, and the *Reference Manual* even places observational meta-analyses *above* the single observational studies that J&J contends are of the highest reliability.⁴³

In fact, the case law says that the analysis undertaken by the PSC’s experts is precisely the kind of analysis that ought to be considered by a jury. As the Court held in *In re Testosterone*:

According to AbbVie, plaintiffs' experts rely on only a few facially favorable studies, while ignoring (1) those studies' flaws, (2) the fact that the studies are inconsistent with one another, and (3) the studies' authors' own unwillingness to conclude that they demonstrate a causal association. As discussed above, a review of plaintiffs' experts' reports

⁴² See PSC Epi. Reply at 6.

⁴³ See *Ref. Man.* at 724-25 (“When ordered from strongest to weakest, systematic review of randomized trials (meta-analysis) is at the top, followed by single randomized trials, **systematic reviews of observational studies, single observational studies**, physiological studies, and unsystematic clinical observations.” (emphasis added)).

reveals that they carefully addressed the merits, flaws, and implications of both favorable and unfavorable studies. [Defendant] is likely correct that no single piece of evidence the experts rely upon is sufficient to support their causation opinions. But the experts have adequately explained why they have reached their conclusions on the basis of the evidence as a whole. *See Milward*, 639 F.3d at 23. The Court's inquiry at this stage is to determine whether the experts "considered sufficient data to employ the methodology," not whether their consideration of the data led to the correct conclusion. *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 766 (7th Cir. 2013). *For an expert conclusion that is subject to doubt, "[i]t is the role of the jury to weigh these sources of doubt."*⁴⁴

As has been previously noted, this is not a summary judgment motion. This Court is not asked to determine whose experts are "right" at this juncture. The question as it relates to the PSC's current motions is whether J&J's experts used the right methodology to reach the conclusions they offer. The PSC has persuasively argued that they have not.

V. CONCLUSION

Based on the foregoing, and the arguments set forth in the PSC's *Daubert* motions and replies and in its responses to J&J's *Daubert* motions, the Court should grant the PSC's *Daubert* motions, and deny J&J's motions.

Respectfully submitted,

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⁴⁴ *In re Testosterone Replacement Therapy Products Liab. Litig. Coordinated Pretrial Proceedings*, 14 C 1748, 2017 WL 1833173, at *13 (N.D. Ill. May 8, 2017), reconsideration denied, 14 C 1748, 2017 WL 2953703 (N.D. Ill. July 11, 2017).

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